

DIESSE DIAGNOSTICA SENESE SpA
 53035 Monteriggioni (SIENA) – Italy – Strada dei Laghi, 39
 Tel. +39 0577319554 FAX +39 0577319020



Sede Legale e Amministrazione
 20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 1 IgG RECOMBINANT

Code 91023

LOT 040 EXPIRY 2023-11

REAGENTS

CODE	LABEL	DESCRIPTION	LOT No.	EXP	NO
PF93021	E8630	MICROPLATE	052	2024-01	1
PF93523	D8630	CONJUGATE	037	2023-11	1
PF93910	1036	NEGATIVE CONTROL	174	2024-02	1
PF93823	B8630	POSITIVE CONTROL	037	2024-02	1
PF91823	C8630	CUT-OFF CONTROL	037	2024-02	1
PF93619	1034	SUBSTRATE-HS	365	2023-11	1
PF30029	1031	DILUENT 3	049-1	2024-02	1
PF93603	1035	WASHING BUFFER 10x	451-1	2024-01	1
PF93602	1032/RISK0	STOP SOLUTION	215	2024-08	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.055	<0,6 CUT-OFF
CUT-OFF CONTROL	0.561	≥ 0.200
POSITIVE CONTROL	2.222	>1,5 CUT-OFF
CV %	7%	≤ 15%

The test has been carried out in accordance with the package insert

TESTED BY: Silvia Sardelli

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 15.09.2022

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an FDA approved method and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.



CERTIFICATE OF ANALYSIS

KIT: **HERPES SIMPLEX 1 IgG RECOMBINANT**
 LOT: **040**
 DATE OF TEST: **12/09/2022**

Code 91023
 Code 91182

METHOD: ACCORDING TO THE PACKAGE INSERT

		FOUND	EXPECTED
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD450 nm	1.910	
	CV%	9%	<20%
2nd PLATE	OD 450nm	N/A	
	CV%	N/A	<20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.895	
	CV%	7%	≤15%
2. BULK CONTROL date: 05/09/2022			
A) Average OD of Cut Off Control	OD 450 nm	0.514	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 12/09/2022			
A) Blank	OD 450 nm	0.039	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.055	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.561	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.222	> 1,5 Cut Off
E) HOMOGENEITY OF CUT-OFF			
	No.	6	
	OD 450 nm	0.600	
	CV%	7%	≤15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY ☐ UNSATISFACTORY

FINAL RESULT: **ACCEPTED**

Date: **12/09/2022**

Signed: 
 Released: Q.C.Manager